

PATENT COOPERATION TREATY

REC'D 07 JUN 2000

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 34104-0074	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/CA98/01137	International filing date (day/month/year) 08/12/1998	Priority date (day/month/year) 04/02/1998
International Patent Classification (IPC) or national classification and IPC C12N15/10		
<p>Applicant THE ONTARIO CANCER INSTITUTE et al.</p> <p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 1 sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the report II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input checked="" type="checkbox"/> Certain observations on the international application 		

Date of submission of the demand 23/08/1999	Date of completion of this report 02.06.00
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I. Basis of the report

1. This report has been drawn on the basis of (substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.):

Description, pages:

1-34 as originally filed

Claims, No.:

6 (part),7-26 as originally filed

1-5,6 (part) as received on 13/05/2000 with letter of 04/05/2000

Drawings, sheets:

1/6-6/6 as originally filed

2. The amendments have resulted in the cancellation of:

the description, pages:

the claims, Nos.:

the drawings, sheets:

3. This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

see separate sheet

4. Additional observations, if necessary:

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V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 4, 6, 14, 15, 18-25
	No: Claims 1-3, 5, 7-13, 16, 17, 26
Inventive step (IS)	Yes: Claims 18-25
	No: Claims 1-17, 26
Industrial applicability (IA)	Yes: Claims 1-16, 18-23, 26
	No: Claims

2. Citations and explanations

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

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Item I.

The amendments filed with the letter dated 04.05.00 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:

- Claim 1, lines 1-3.

No basis for these amendments can be found in the application as filed.

Consequently, this report has been established as if said amendments had not been made (Rule 70.2(c) PCT), i.e. **has been established on the basis of claims 1-26 as originally filed.**

Item V.

Reference is made to the following documents:

- D1: J. Bacteriol., 172(2), 1990, pp.653-8.
- D2: J. Bacteriol., 173(3), 1991, pp.1151-60.
- D3: Biotechniques, 17(6), 1994, pp.1132-39.
- D_A: Bray et al., Abstract no. 428.
- D_B: Bray et al., Abstract no. 429.

- I) 1) Document D1 discloses a method for identifying cytotoxic mutant proteins capable of binding to a target cell, comprising steps (A), (B) and (C) of claim 1. The specific embodiments recited in dependent claims 2, 3, 5, 7-13 and 16 are also disclosed in D1. The method of claim 17 is also described in D1. Thus, D1 destroys the novelty of present claims 1-3, 5, 7-13 and 16-17 (Article 33.2 PCT).
- 2) D2 as well destroys the novelty of claims 1-3, 5, 7-13 and 16-17 (Article 33.2 PCT).

II) The features of claims 4, 14, 15 and claim 6 (see e.g. document D3) are merely straightforward possibilities from which the skilled person would select, in accord-

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ance with circumstances, without the exercise of inventive skill. Therefore, the subject-matter of claims 4, 14, 15 and 6 lack an inventive step (Article 33.3 PCT) in view of D1 or D2 combined with the skilled person's general knowledge and D3, respectively.

- III) Since said "suitable supports" are not defined in claim 26, the kit comprising said heteromeric protein toxin is anticipated by any disclosure of a heteromeric protein toxin. Claim 26 lacks novelty over *inter alia* D1 or D2.
- IV) For the assessment of the present claims 17, 24 and 25 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.
- V) This Report is based on the assumption that all claims enjoy priority rights from the filing date of the priority document. If it later turns out that this is not correct, the documents D_A and D_B cited in the international search report could become relevant.

Item VIII.

Claim 21 is not clear. It is directed to a method for constructing diagnostic probes for detecting the presence of a cell surface marker. Only step (A) is compulsory, steps (B) and (C) being optional. However, step (A) is not sufficient to perform the detection. At least step (C) should be performed. Thus, the word "optionally" renders the claim unclear (Article 6 PCT).